



## **Challenge TB - Core Bedaquiline Coordination**

**Year 2**

### **Quarterly Monitoring Report October-December 2015**

**Submission date: February 4, 2016**

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*Cover photo:*

*Group work of CTB consultants (middle) with head of SES MoH, representatives of M&E of NTP, head of the Project Hope and Defeat TB representatives (from left to right) on the partners meeting on preparation Plan for introduction of the new TB drugs and shortened regimens for MDR TB patients in Kyrgyzstan*

*Credit to Bakyt Myrzaliev*

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### **Disclaimer**

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## 1. Quarterly Overview

Country	Core Bedaquiline Coordination
Lead Partner	KNCV Tuberculosis Foundation
Other partners	
Workplan timeframe	October 2015 – September 2016
Reporting period	October - December 2015

### Summary progress report:

The work plan was approved in November 2015.

Since then a core project team was formed, consisting of:

- Agnes Gebhard (AG) - overall technical lead;
- Susan van den Hof (AH) - leading the operational research and pharmacovigilance (PV);
- Antonia Kwiecien (AK) - SIAPS, leading the PSCM aspects.

Other team members are:

- Gunta Dravniece - clinical management;
- Ieva Leimane - training and capacity building;
- Edine Tiemersma – Pharmacovigilance and operational research;
- Project coordinator –recruitment in process.

The project coordinator was recruited in December and will start work with KNCV mid-March 2016; till that time his functions are taken up by Agnes Gebhard and Susan van den Hof.

Mischa Heeger is the focal point for this project in the PMU; Millicent Ngicho is the project officer.

The Bedaquiline (BDQ) core coordination project is funding the development of a strategy, generic training modules and protocols. These materials will be available for all countries. In Challenge TB countries TA to the implementation and roll-out is funded through CTB country funds.

This core project supports additional technical assistance visits to CTB countries when needed or where funding is limited. This report will highlight both what has been achieved in countries, as what has been developed and achieved under the Core project.

### Activities funded by the core project:

The project was introduced to Challenge TB coalition partners on December 5<sup>th</sup> during the CTB Partners Representatives meeting in Cape Town. The presentation, including the summary of the baseline of BDQ implementation in CTB countries is attached to this report as annex 1.

The BDQ core project key consultants participate in and contribute to GDI -Task force meetings on the introduction of new drugs (one planned on Ukraine beginning of February 2016).

A draft operational research protocol was made, which will be finalized with input from partners in January/February 2016.

The team compiled an inventory of available training and supportive materials, to be completed and used from the first quarter of 2016.

### Support to programmatic introduction of Bedaquiline in Kazakhstan (limited TA, funded by the core project).

During The Union conference in Cape Town a meeting took place with USAID, KNCV and the CTB CAR team on a possible CTB supported (from the core project) technical assistance to the programmatic introduction of BDQ in Kazakhstan in addition to the implementation by PIH of the END TB project, which covers only a limited number of patients. This TA is requested by the director of the NTCP, Dr. Abildayev

Agreed was that only limited TA will be available, to complement the ENDTB project implementation. The regional USAID mission (Arman Toktabayanov) and the regional KNCV office (Svetlana Pak and Maria Idrissova) will bring this proposal back to the NTP.

This was done by Arman Toktabayanov and shared with Svetlana Pak in a meeting with USAID regional office, Partners in Health (PIH) and the KNCV regional office (Notes attached as annex 2). Dr. Abildayev is interested in this approach and PIH indicated their willingness to collaborate.

Identified fields of possible KNCV involvement are:

1. Assess the situation in the regions to identify the program gaps/challenges and needs to create conditions for proper management of patients on new drugs;
2. Help NTP in calculation of needs in BDQ and companion drugs;
3. Build capacity of medical personnel in clinical management of patients on new drugs and regimens, and support aDSM ( active Drug Management and Monitoring) system in the regions;
4. Introduce the guide, SOPs and forms in the region;
5. Monitor clinical management of patients on new drugs and regimens in the regions.

One of the important questions is who will buy the companion drugs. There is no clear answer yet. This issue needs further discussion with NTP and estimation of drugs' needs is necessary. EndTB project will procure new drugs and companion drugs for five sites. Here KNCV could provide TA. Further meetings between KNCV Regional Office and PIH are planned for coordination of the approach.

#### Progress in CTB countries since the program inception:

- Ukraine: Assessment and planning workshop done, introduction protocol drafted, enrollment criteria, regimens, diagnostic algorithm developed and discussed with key national experts;
- Tajikistan: Workshop/training on PV done, forms under development, introduction protocol drafted;
- Indonesia: started treatment of patients with BDQ by October, first review of PV protocol implementation done in November
- Vietnam: started treatment of patients on BDQ in December;
- Kyrgyzstan: national plan on introduction of new drugs drafted, introduction protocol drafted, enrollment criteria, diagnostic algorithm under discussion with key national experts;
- Nigeria: introductory workshop facilitated.

*Related to the CTB countries (Ukraine, Tajikistan, Vietnam, Kyrgyzstan and Nigeria) more detailed information can be found in the respective CTB country Quarterly Monitoring Reports.*

#### Progress in SIAPS supported countries

- Georgia – Enrolling since September ( reported numbers are still combined with MSF totals)
- Philippines – BDQ arrived in country, will start enrolment pre-XDR patients in February; training on XDR treatment was postponed till June
- Swaziland – Organizing a launch event will start BDQ treatment in February
- Kenya – Stakeholders meeting took place is writing protocol – may start treatment by September
- Uganda - First stakeholders meeting recently done, writing the protocol

#### **Technical/administrative challenges and actions to overcome them:**

The Technical Project Coordinator will start work mid-March; ad interim Agnes Gebhard and Susan van den Hof fulfill this task.

## 2. Year 2 activity progress

Sub-objective 3. Patient-centered care and treatment						
Planned Key Activities for the Current Year	Activity #	Planned Milestones				Milestone
		Oct-Dec 2015	Jan-Mar 2016	Apr-Jun 2016	Year end	Oct-Dec
Development of detailed strategy per CTB country	3.2.1	2 countries	4 countries (planned to include Tajikistan, Nigeria)	6 countries (planned to include Kazakhstan Botswana DRC)	8 countries (planned to include Ethiopia Burma)	In Ukraine and Kyrgyzstan a strategy was developed; ongoing. Vietnam and I where strategy developed under TBCAREI APA4 APA1 funding, enrolling patients BDQ.
Development of generic training modules, to be used in all countries	3.2.2	Drafts ready: based on inventory and CTB/SIAPS developed modules	Full set ready: development of additionally required modules	Dissemination of training modules to CTB partners. Use of training modules in countries ready to start using new drugs and regimens (Kyrgyzstan, Ukraine, Tajikistan)	Use of training modules in other countries ready to start using new drugs and regimens (to be determined)	An inventory of modules was reviewed checking with South Africa, CTB, WHO, CTB early implementation countries etc.
Development of generic materials and protocols, to be adjusted per country	3.2.3	Draft ready: Development draft generic protocol	Full set ready: Share generic protocol and materials with partners for comments and finalize  Development country-specific protocols and materials (Kyrgyzstan, Ukraine, Tajikistan)  Orientation/capacity building CTB partners	Capacity building rGLCs and others	Continued updating generic materials base  Capacity building rGLCs and others	The development of several of the documents is completed by KNCV (protocol, SOPs, TA guide) and (electronic PV system, PVIMS)
Coordination with USAID/SIAPS/CTB partners and support data collection for evidence related to ND&R introduction	3.2.4	CTB partners appointed focal points for BDQ TA Core	- all CTB FP's have up to date information on the project - identify needs for capacity building on	Data collection	Data collection	List of focal points available.  Coordinating meeting among the CTB partners planned February 8 <sup>th</sup>

		Project	ND&R introduction among CTB partners - partners familiar with project M&E  Integration of qualitative M&E on ND&R implementation into the CTB management system			
Additional support visits from HQ to Challenge TB countries when needed	3.2.5	1 country	3 countries	4 countries	5 countries	First meeting in Kazakhstan in

### 3. Challenge TB-supported international visits (technical and management-related trips)

#	Partner	Name of consultant	Planned quarter				Specific mission objectives	Status (cancelled, pending, completed)	Date completed
			Q 1	Q 2	Q 3	Q 4			
1	KNCV	Susan van den Hof, Gunta Dravniece	x				<b><u>Kyrgyzstan</u></b> Facilitation of WS on development of national for the introduction of new drugs and short regimens	Complete	28.09.-03.10.15
2	KNCV/PATH	Gunta Dravniece	x				<b><u>Ukraine</u></b> Assessment of the M/XDR-TB situation, preparedness of the NTP for implementation of shortened regimens and new drugs	Complete	19.-22.11
3	KNCV	Gunta Dravniece	x				<b><u>Nigeria</u></b> Facilitation of introductory WS on new drugs and short regimens	Complete	23.-27.11
4	KNCV/PATH	Gunta Dravniece	x				<b><u>Ukraine</u></b> Development of OR protocol for short regimens and new drugs	Complete	30.11.-04.12.15
5	KNCV/WHO	Svetlana Pak					<b><u>Kyrgyzstan</u></b> Co facilitation the workshop on aDSM	Complete	08 – 11.12

6	KNCV	Svetlana Pak					<b>Tajikistan</b> Co facilitation of aDSM workshop	Complete	13 – 18.
7	KNCV	Suzanne Verver					<b>Tajikistan</b> Co facilitation of aDSM workshop	Complete	13 – 18.
8	KNCV	Agnes Gebhard					Vietnam monitoring mission on BDQ	Complete	12-19.1.
9	KNCV	Edine Tiemersma					Indonesia monitoring mission for PV	Complete	KNCV
Total number of visits conducted (cumulative for fiscal year)								9 (reported in the country	
Total number of visits conducted from core project funding								0	
Total number of visits planned in the approved core project work plan total period								5 (0 for the reporting period)	
Percent of planned international consultant visits conducted								0%	

#### Annexes:

- 1) Presentation of Bedaquiline Core Project as introduced to Challenge TB coalition partners on December 5<sup>th</sup> during the CTB Partners Representatives meeting in Cape Town



Annex 1 2015 11 23  
NDR Core project upc

- 2) Notes of meeting USAID regional office Almaty, KNCV Regional Office Almaty, Partners in Health (PIH)



Annex 2  
TA\_BDQ\_KZ\_meeting

- 3) List of CTB coalition partners' contact persons for the Bedaquiline Core Project